

Office Action Summary	Application No. 10/065,280	Applicant(s) LEUNG ET AL.	
	Examiner KATHERINE DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3,6-9,12-20,22,31-38,51-62,69,70 and 77-82 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-3,6-9,12-20,22,31-38,51-62,69,70 and 77-82 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date <u>11/17/2011</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The following is in response to the amendment filed November 8, 2011.
2. Claims 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 are currently pending.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-3, 12-15, and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Buncke (US 5,931,855). Buncke discloses the invention substantially as claimed including a barbed suture (Figures 9-11) comprising an elongate body having a first end and a second end and a plurality of barbs (16) projecting from the body. The barbs are arranged in a multiple spiral disposition wherein the barbs are spaced longitudinally along the body such that a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb (Figures 9-11; col 4, ln 58-59; col 9, ln 5-8). In a first barb portion (55a) all of the barbs are only facing toward a first end of the elongate body and in a second barb portion (55b) all of the barbs are only facing toward a second end of the elongate body (col 6, ln 60-67). The barbs are cut from a suture having a circular cross-section (Fig 1A), wherein the base of the barb projects from an arcuate line transverse to the longitudinal axis of the suture body. Since the line from which the barb projects is defined by the outer circumference of the suture body, the line is arcuate. The suture may be made of a non-absorbable material including polyester or made of a bio-absorbable material including polylactide or polyglycolide (col 1, ln 20-23).

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 6-9, 16-20, 22, 51-62, 69, 70, and 77-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (US 5,931,855). Buncke discloses the invention substantially as claimed including a barbed suture (Figures 9-11) comprising an elongate body having a first end and a second end and a plurality of barbs (16) projecting from the body. The barbs are arranged in a multiple spiral disposition wherein the barbs are spaced longitudinally along the body such that a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb (Figures 9-11; col 4, ln 58-59; col 9, ln 5-8). In a first barb portion (55a) all of the barbs are only facing toward a first end of the elongate body and in a second barb portion (55b) all of the barbs are only facing toward a second end of the elongate body (col 6, ln 60-67). The barbs are cut from a suture having a circular cross-section (Fig 1A), wherein the base of the barb projects from a line transverse to the longitudinal axis of the suture body. Since the line from which the barb projects is defined by the outer circumference of the suture body, the line is arcuate. The suture may be made of a non-absorbable material including polyester or made of a bio-absorbable material including polylactide or polyglycolide (col 1, ln 20-23).

However, Buncke does not disclose the specific dimensions of the spirality angle, the barb cut angle, the ratio of the barb cut depth to the suture diameter, the ratio of the barb cut length to the suture diameter, or the ratio of the barb cut distance to the suture diameter. Applicant has not disclosed that having a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, or a ratio of barb cut distance to suture diameter of 0.1-6

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solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of Buncke, or applicant's invention, would perform equally well with the suture having any appropriate dimension. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the suture of Buncke such that the suture had a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, and a ratio of barb cut distance to suture diameter of 0.1-6 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the suture of Buncke. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the suture of Buncke to incorporate the above parameters since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or the an optimum value involves only routine skill in the art (see *In re Aller*, 105 USPQ 233, *In re Boesch*, 617 F.2d 272, 205 USPQ 215, and MPEP 2144.05).

Additionally, Buncke does not disclose the suture is twisted 2 to 17 times per inch to form the multiple spiral disposition. However, the claim language regarding twisting the suture 2 to 17 times per inch is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden shifted to the applicant to show an unobvious *structural* difference in the product. The Examiner contends Buncke discloses a suture having barbs in a multiple spiral disposition (Figures 9-11).

Response to Arguments

7. Applicant's arguments filed November 8, 2011 have been fully considered but they are not persuasive.

8. Applicant argues Buncke does not disclose the barbs have an underside projecting "from the body along a line transverse to the longitudinal axis of the body, the line being arcuate".

Applicant agrees the outer circumference of the suture body is circular and thus a line transverse to the longitudinal axis of the suture body is arcuate. However, Applicant contends the underside of the barb does not project from the outer circumference of the suture body. The Examiner respectfully disagrees and notes the limitation that the underside of the barb "projects from" an arcuate reference line does not require the underside of the barb to have an arcuate base at the location where the barb is attached to the suture body. The limitation is interpreted such that the barb (including the top side and underside) projects from, or extends from, the suture body, which has an arcuate circumference. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached Monday through Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
November 17, 2011

/Katherine M Dowe/
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734